REMARKS

Claims 1-34 were pending in the application. Claim 14 has been amended. Upon entry of these amendments, Claims 1-34 will be pending and under active consideration. Claim 1 is independent.

I. Objections to the Claims

Claim 14 has been amended herein to clarify how to determine the yield point of the middle layer. This amendment is supported fully by the specification as originally filed and does not represent new matter. In particular, support for the amendment to Claim 14 may be found at page 19, lines 29-21.

Copies of DIN EN ISO 527-1 to 527-3 and DIN 58950-1 are submitted herewith. A person of skill in the art can readily interpret the test conditions and the phrase "hot water spraying process" in the claims.

II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-9, 14 and 20-33 are rejected under 35 USC 103(b) over Heilmann et al. in view of Collette et al. Claims 10-13 and 15-17 are rejected over Heilmann et al. and Collette et al. in view of Fujii et al. and Claim 34 is rejected over Heilmann and Collette in view of Andersson et al.

The Office Action alleges that Heilmann et al. teaches one of ordinary skill in the art to determine appropriate ranges of thickness, melting points, and VICAT temperatures to reach a desired end use through routine optimization. The argument is that Collette et al. discloses propylene without a yield point (page 1, line 34), so it would have been obvious to use it in a multi-layer film if lack of a yield point were important. Applicants traverse respectfully.

Heilmann fails to teach or suggest a multilayer film having no measurable yield point. In the prsent specification the drawback of the Heilmann file are discussed extensively (page 8, lines 8 – 31; EP-A 0739713 is the European counterpart of Heilmann.

The Collette patent is not concerned with a medical bag. There are not hints with regard to the improvements achievable by the use of these polymers. As mentioned on page 1, lines 24-25, the object of Collette was to provide a polypropylene with elastic properties

that can be produced as a direct reaction product using a practical process. No further improvements are mentioned in the Collette document. There is no suggest that the elastic propylene polymers are superior over other, and hence, there is no suggestion to use the Collette polymers in the Heilmann multi-layer file. The same is true of Heilmann, i.e., there is no suggestion to use a polymer such as that disclosed in Collette. Consequently, the improvement achieved by the present invention was not foreseeable by a person of ordinary skill in the and combination of Collette with Heilmann.

Since Heilmann has been shown, by way of the comparative examples in Table 3, to not teach or even suggest a multi-layer film that displays no measurable yield point according to DIN EN ISO 527-1 to –3 1996, Applicants respectfully submit that a *prima facie* case of obviousness has not been met with respect to the invention as presently claimed.

The comparative examples show that blends comprising polypropylene having no yield *can* lead to a multi-layer film having a yield point. Comparative examples 9 – 11, which show that a polymer having no yield does not inevitably give a multi-layer film having no yield. Please consider that PPC3 has been used as a blend with PPT3

The present examples also show that a multi-layer film having no yield can also be produced by the use of polypropylene having a yield (see Table 3, Example 13). Consequently, knowledge of the Collette document would not suggest how to construct a multi-layer film having no yield in the structure as claimed.

Surprisingly, the present invention provides *multi-layer* films having no yield at all, which is not something suggested by a combination of Heilmann and Collette, together or separately.

Regarding the Fuji document, all polymer materials disclosed in it have a specific elastic modulus. Consequently, it would not have been easy for a person skilled the art to develop a multi-layer film having no yield.

In view of the above, Applicants respectfully submit that a *prima facie* case of obviousness has not been met with respect to the invention as presently claimed. Accordingly, Applicants request respectfully that the rejections of Claims 1-34 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at **(202) 625-3500**. All correspondence should be directed to our address given below.

AUTHORIZATION

Applicants believe there is no additional fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

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Dated: March 7, 2005

Attachments: DIN EN ISO 527-1 (37 pages)

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DEUTSCHE NORM April 1996

Plastics

General principles for the determination of tensile properties (ISO 527-1:1993 + Corr 1:1994)

English version of DIN EN ISO 527-1

DIN EN ISO 527-1

This standard incorporates the English version of ISO 527-1.

ICS 83.080.00; 83.120

Supersedes parts of DIN 53455, August 1981 edition and DIN 53457, October 1987 edition.

Descriptors: Plastics, testing, tensile strength.

Kunststoffe; Bestimmung der Zugeigenschaften. Teil 1: Allgemeine Grundsätze (ISO 527-1:1993 + Corr 1:1994)

European Standard EN ISO 527-1:1996 has the status of a DIN Standard.

A comma is used as the decimal marker.

National foreword

This standard has been published in accordance with a decision taken by CEN/TC 249 to adopt, without alteration, International Standard ISO 527-1 as a European Standard.

The responsible German body involved in its preparation was the *Normenausschuß Kunststoffe* (Plastics Standards Committee).

DIN 50014 is the standard corresponding to International Standard ISO 291 referred to in clause 2 of the EN.

Amendments

Parts of DIN 53455, August 1981 edition and DIN 53457, October 1987 edition, have been superseded by the specifications of EN ISO 527-1, which is identical to ISO 527-1.

It should be noted that the specifications regarding the determination of the modulus of elasticity in tension given in the October 1987 edition of DIN 53457 have been included in this standard.

Previous editions

DIN 53371: 1955-10, 1959-09; DIN 53455: 1952-10, 1968-04, 1981-08; DIN 53457: 1968-05, 1987-06, 1987-10.

Standard referred to

(and not included in **Normative references**)

DIN 50014 Artificial climates in technical applications; standard atmospheres

EN comprises 10 pages.

Beuth Verlag GmbH, Berlin, has the exclusive right of sale for German Standards (DIN-Normen).

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 527-1

February 1996

ICS 83.080.00; 83.120

Descriptors: Plastics, testing, tensile strength.

English version

Plastics

Determination of tensile properties
Part 1: General principles
(ISO 527-1 : 1993 + Corr 1: 1994)

Plastiques; détermination des propriétés en traction. Partie 1: Principes généraux (ISO 527-1 : 1993 + Rectificatif technique 1: 1994)

Kunststoffe; Bestimmung der Zugeigenschaften. Teil 1: Allgemeine Grundsätze (ISO 527-1 : 1993 + Corr 1 : 1994)

This European Standard was approved by CEN on 1994-12-14 and is identical to the ISO Standard as referred to.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN ISO 527-1 : 1996 E

Foreword

International Standard

ISO 527-1:1993 Plastics: determination of tensile properties,

which was prepared by ISO/TC 61 'Plastics' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 249 'Plastics' as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by August 1996 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of the International Standard ISO 527-1:1993 + Corr 1:1994 was approved by CEN as a European Standard, taking into account the following Corrigendum:

Throughout the text, delete the expression 'Young's modulus' or replace it by 'tensile modulus of elasticity', depending on the context. This concerns definition 4.6, subclause 10.3 (twice), figure 1 and annex A (title plus second paragraph).

1 Scope

1.1 This part of ISO 527 specifies the general principles for determining the tensile properties of plastics and plastic composites under defined conditions.

Several different types of test specimen are defined to suit different types of material which are detailed in subsequent parts of ISO 527.

1.2 The methods are used to investigate the tensile behaviour of the test specimens and for determining the tensile strength, tensile modulus and other aspects of the tensile stress/strain relationship under the conditions defined.

1.3 The methods are selectively suitable for use with the following range of materials:

— rigid and semirigid thermoplastics moulding and extrusion materials, including filled and reinforced compounds in addition to unfilled types; rigid and semirigid thermoplastics sheets and films;

— rigid and semirigid thermosetting moulding materials, including filled and reinforced compounds; rigid and semirigid thermosetting sheets, including laminates;

— fibre-reinforced thermoset and thermoplastics composites incorporating unidirectional or non-unidirectional reinforcements such as mat, woven fabrics, woven rovings, chopped strands, combination and hybrid reinforcements, rovings and milled fibres; sheets made from pre-impregnated materials (prepregs);

— thermotropic liquid crystal polymers.

The methods are not normally suitable for use with rigid cellular materials or sandwich structures containing cellular material.

1.4 The methods are applied using specimens which may be either moulded to the chosen dimensions or machined, cut or punched from finished and semifinished products such as mouldings, laminates, films and extruded or cast sheet. In some cases a multipurpose test specimen (see ISO 3167:1993, *Plastics — Preparation and use of multipurpose test specimens*), may be used.

1.5 The methods specify preferred dimensions for the test specimens. Tests which are carried out on specimens of different dimensions, or on specimens which are prepared under different conditions, may produce results which are not comparable. Other factors, such as the speed of testing and the conditioning of the specimens, can also influence the results. Consequently, when comparative data are required, these factors must be carefully controlled and recorded.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 527. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 527 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 291:1977, *Plastics — Standard atmospheres for conditioning and testing.*

ISO 2602:1980, *Statistical interpretation of test re-*

sults — Estimation of the mean — Confidence interval.

ISO 5893:1985, *Rubber and plastics test equipment — Tensile, flexural and compression types (constant rate of traverse) — Description.*

3 Principle

The test specimen is extended along its major longitudinal axis at constant speed until the specimen fractures or until the stress (load) or the strain (elongation) reaches some predetermined value. During this procedure the load sustained by the specimen and the elongation are measured.

4 Definitions

For the purposes of this part of ISO 527, the following definitions apply.

4.1 gauge length, L_0: Initial distance between the gauge marks on the central part of the test specimen; see figures of the test specimens in the relevant part of ISO 527.

It is expressed in millimetres (mm).

4.2 speed of testing, v: Rate of separation of the grips of the testing machine during the test.

It is expressed in millimetres per minute (mm/min).

4.3 tensile stress, σ (engineering): Tensile force per unit area of the original cross-section within the gauge length, carried by the test specimen at any given moment.

It is expressed in megapascals (MPa) [see 10.1, equation (3)].

4.3.1 tensile stress at yield; yield stress, σ_y: First stress at which an increase in strain occurs without an increase in stress.

It is expressed in megapascals (MPa).

It may be less than the maximum attainable stress (see figure 1, curves b and c).

4.3.2 tensile stress at break, σ_B: The tensile stress at which the test specimen ruptures (see figure 1).

It is expressed in megapascals (MPa).

4.3.3 tensile strength, σ_M: Maximum tensile stress sustained by the test specimen during a tensile test (see figure 1).

It is expressed in megapascals (MPa).

4.3.4 tensile stress at x **% strain** (see 4.4), σ_x: Stress at which the strain reaches the specified value x expressed in percentage.

It is expressed in megapascals (MPa).

It may be measured for example if the stress/strain curve does not exhibit a yield point (see figure 1, curve d). In this case, x shall be taken from the relevant product standard or agreed upon by the interested parties. However, x must be lower than the strain corresponding to the tensile strength, in any case.

4.4 tensile strain, ε: Increase in length per unit original length of the gauge.

It is expressed as a dimensionless ratio, or in percentage (%) [see 10.2, equations (4) and (5)].

It is used for strains up to yield point (see 4.3.1); for strains beyond yield point see 4.5.

4.4.1 tensile strain at yield, ε_y: Tensile strain at the yield stress (see 4.3.1 and figure 1, curves b and c).

It is expressed as a dimensionless ratio, or in percentage (%).

4.4.2 tensile strain at break, ε_B: Tensile strain at the tensile stress at break (see 4.3.2), if it breaks without yielding (see figure 1, curves a and d).

It is expressed as a dimensionless ratio, or in percentage (%).

For breaking after yielding, see 4.5.1.

4.4.3 tensile strain at tensile strength, ε_M: Tensile strain at the point corresponding to tensile strength (see 4.3.3), if this occurs without or at yielding (see figure 1, curves a and d).

It is expressed as a dimensionless ratio or in percentage (%).

For strength values higher than the yield stress, see 4.5.2.

4.5 nominal tensile strain, ε_t: Increase in length per unit original length of the distance between grips (grip separation).

It is expressed as a dimensionless ratio, or in percentage (%) [see 10.2, equations (6) and (7)].

It is used for strains beyond yield point (see 4.3.1). For strains up to yield point, see 4.4. It represents the total relative elongation which takes place along the free length of the test specimen.

4.5.1 nominal tensile strain at break, ε_{tB}: Nominal tensile strain at the tensile stress at break (see 4.3.2), if the specimen breaks after yielding (see figure 1, curves b and c).

It is expressed as a dimensionless ratio, or in percentage (%).

For breaking without yielding, see 4.4.2.

4.5.2 nominal tensile strain at tensile strength, ε_{tM}: Nominal tensile strain at tensile strength (see 4.3.3), if this occurs after yielding (see figure 1, curve b).

It is expressed as a dimensionless ratio, or in percentage (%).

For strength values without or at yielding, see 4.4.3.

4.6 modulus of elasticity in tension; Young's modulus, E_t: Ratio of the stress difference σ_2 minus σ_1 to the corresponding strain difference values $\varepsilon_2 = 0{,}002\,5$ minus $\varepsilon_1 = 0{,}000\,5$ (see figure 1, curve d and 10.3, equation (8)).

It is expressed in megapascals, (MPa).

This definition does not apply to films and rubber.

NOTE 1 With computer-aided equipment, the determination of the modulus E_t using two distinct stress/strain points can be replaced by a linear regression procedure applied on the part of the curve between these mentioned points.

4.7 Poisson's ratio, μ: Negative ratio of the tensile strain ε_n, in one of the two axes normal to the direction of pull, to the corresponding strain ε in the direction of pull, within the initial linear portion of the longitudinal versus normal strain curve.

It is expressed as a dimensionless ratio.

Poisson's ratio is indicated as μ_b (width direction) or μ_h (thickness direction) according to the relevant axis. Poisson's ratio is preferentially used for long-fibre-reinforced materials.

5 Apparatus

5.1 Testing machine

5.1.1 General

The machine shall comply with ISO 5893, and meet the specifications given in 5.1.2 to 5.1.5, as follows.

5.1.2 Speeds of testing

The tensile-testing machine shall be capable of maintaining the speeds of testing (see 4.2) as specified in table 1.

Table 1 — Recommended testing speeds

Speed mm/min	Tolerance %
1	± 20 [1)]
2	± 20 [1)]
5	± 20
10	± 20
20	± 10
50	± 10
100	± 10
200	± 10
500	± 10

1) These tolerances are smaller than those indicated in ISO 5893.

5.1.3 Grips

Grips for holding the test specimen shall be attached to the machine so that the major axis of the test specimen coincides with the direction of pull through the centreline of the grip assembly. This can be achieved, for example, by using centring pins in the grips. The test specimen shall be held such that slip relative to the grips is prevented as far as possible and this shall preferably be effected with the type of grip that maintains or increases pressure on the test specimen as the force applied to the test specimen increases. The clamping system shall not cause premature fracture at the grips.

5.1.4 Load indicator

The load indicator shall incorporate a mechanism capable of showing the total tensile load carried by the test specimen when held by the grips. The mechanism shall be essentially free from inertia lag at the specified rate of testing, and shall indicate the load with an accuracy of at least 1 % of the actual value. Attention is drawn to ISO 5893.

5.1.5 Extensometer

The extensometer shall comply with ISO 5893. It shall be capable of determining the relative change in the gauge length on the test specimen at any time during the test. It is desirable, but not essential, that this instrument should automatically record this change. The instrument shall be essentially free from inertia lag at the specified speed of testing, and shall be capable of measuring the change of gauge length with an accuracy of 1 % of the relevant value or better. This corresponds to ± 1 µm for the measurement of the modulus, based on a gauge length of 50 mm.

When an extensometer is attached to the test specimen, care shall be taken to ensure that any distortion of or damage to the test specimen is minimal. It is essential that there is no slippage between the extensometer and the test specimen.

The specimens may also be instrumented with longitudinal strain gauges, the accuracy of which shall be 1 % of the relevant value or better. This corresponds to a strain accuracy of 20×10^{-6} (20 microstrain) for the measurement of the modulus. The gauges, surface preparation and bonding agents should be chosen to exhibit adequate performance on the subject material.

5.2 Devices for measuring width and thickness of the test specimens

5.2.1 Rigid materials

A micrometer or its equivalent, capable of reading to 0,02 mm or less and provided with means for measuring the thickness and width of the test specimens, shall be used. The dimensions and shape of the anvils shall be suitable for the specimens being measured and shall not exert a force on the specimen such as to detectably alter the dimension being measured.

5.2.2 Flexible materials

A dial-gauge, capable of reading to 0,02 mm or less and provided with a flat circular foot which applies a pressure of 20 kPa ± 3 kPa, shall be used for measuring the thickness.

6 Test specimens

6.1 Shape and dimensions

See that part of ISO 527 relevant to the material being tested.

6.2 Preparation of specimens

See that part of ISO 527 relevant to the material being tested.

6.3 Gauge marks

If optical extensometers are used, especially for thin sheet and film, gauge marks on the specimen are necessary to define the gauge length. These shall be approximately equidistant from the midpoint, and the distance between the marks shall be measured to an accuracy of 1 % or better.

Gauge marks shall not be scratched, punched or impressed upon the test specimen in any way that may damage the material being tested. It must be ensured that the marking medium has no detrimental effect on the material being tested and that, in the case of parallel lines, they are as narrow as possible.

6.4 Checking the test specimens

The specimens shall be free of twist and shall have mutually perpendicular pairs of parallel surfaces. The surfaces and edges must be free from scratches, pits, sink marks and flash. The specimens shall be checked for conformity with these requirements by visual observation against straightedges, squares and flat plates, and with micrometer calipers. Specimens showing observed or measured departure from one or more of these requirements shall be rejected or machined to proper size and shape before testing.

6.5 Anisotropy

See that part ISO 527 relevant to the material being tested.

7 Number of test specimens

7.1 A minimum of five test specimens shall be tested for each of the required directions of testing and for the properties considered (modulus of elasticity, tensile strength etc.). The number of measurements may be more than five if greater precision of the mean value is required. It is possible to evaluate this by means of the confidence interval (95 % probability, see ISO 2602).

7.2 Dumb-bell specimens that break within the shoulders or the yielding of which spreads to the width of the shoulders shall be discarded and further specimens shall be tested.

7.3 Data from parallel-sided specimens where jaw slippage occurs, or where failure occurs within 10 mm of either jaw, or where an obvious fault has resulted in premature failure, shall not be included in the analysis. Repeat tests shall be carried out on new test specimens.

Data, however variable, shall not be excluded from the analysis for any other reason, as the variability in such data is a function of the variable nature of the material being tested.

NOTE 2 When the majority of failures falls outside the criteria for an acceptable failure, the data may be analysed statistically, but it should be recognized that the final result is likely to be conservative. In such instances, it is preferable for the tests to be repeated with the dumb-bell specimens to reduce the possibility of unacceptable results.

8 Conditioning

The test specimen shall be conditioned as specified in the appropriate standard for the material concerned. In the absence of this information, the most appro-

priate condition from ISO 291 shall be selected, unless otherwise agreed upon by the interested parties.

9 Procedure

9.1 Test atmosphere

Conduct the test in the same atmosphere used for conditioning the test specimen, unless otherwise agreed upon by the interested parties, e.g. for testing at elevated or low temperatures.

9.2 Dimensions of test specimen

Measure the width b to the nearest 0,1 mm and the thickness h to the nearest 0,02 mm at the centre of each specimen and within 5 mm of each end of the gauge length.

Record the minimum and maximum values for width and thickness of each specimen and make sure that they are within the tolerances indicated in the standard applicable for the given material.

Calculate the arithmetic means for the width and thickness of each specimen, which shall be used for calculation purposes.

NOTES

3 In the case of injection-moulded specimens, it is not necessary to measure the dimensions of each specimen. It is sufficient to measure one specimen from each lot to make sure that the dimensions correspond to the specimen type selected (see the relevant part of ISO 527). With multiple-cavity moulds, ensure that the dimensions of the specimens are the same for each cavity.

4 For test specimens stamped from sheet or film material, it is permissible to assume that the mean width of the central parallel portion of the die is equivalent to the corresponding width of the specimen. The adoption of such a procedure should be based on comparative measurements taken at periodic intervals.

9.3 Clamping

Place the test specimen in the grips, taking care to align the longitudinal axis of the test specimen with the axis of the testing machine. To obtain correct alignment when centring pins are used in the grips, it is necessary to tension the specimen only slightly before tightening the grips (see 9.4). Tighten the grips evenly and firmly to avoid slippage of the test specimen.

9.4 Prestresses

The specimen shall not be stressed substantially prior to test. Such stresses can be generated during centring of a film specimen, or can be caused by the clamping pressure, especially with less rigid materials.

The residual stress σ_0 at the start of a test shall not exceed the following value, for modulus measurement:

$$|\sigma_0| \leqslant 5 \times 10^{-4} E_t \qquad \ldots (1)$$

which corresponds to a prestrain of $\varepsilon_0 \leqslant 0{,}05\ \%$, and for measuring relevant stresses σ, e.g. $\sigma = \sigma_y$, σ_M or σ_B:

$$\sigma_0 \leqslant 10^{-2} \sigma \qquad \ldots (2)$$

9.5 Setting of extensometers

After balancing the prestresses, set and adjust a calibrated extensometer to the gauge length of the test specimen, or provide longitudinal strain gauges, in accordance with 5.1.5. Measure the initial distance (gauge length) if necessary. For the measurement of Poisson's ratio, two elongation- or strain-measuring devices shall be provided to act in the longitudinal and normal axes simultaneously.

For optical measurements of elongation, place gauge marks on the specimen in accordance with 6.3.

The elongation of the free length of the test specimen, measured from the movement of the grips, is used for the values of the nominal tensile strain ε_t (see 4.5).

9.6 Testing speed

Set the speed of testing in accordance with the appropriate standard for the material concerned. In the absence of this information, the speed of testing should be agreed between the interested parties in accordance with table 1.

It may be necessary or desirable to adopt different speeds for the determination of the elastic modulus, of the stress/strain properties up to the yield point, and for the measurement of tensile strength and maximum elongation. For each testing speed, seperate specimens shall be used.

For the measurement of the modulus of elasticity, the selected speed of testing shall provide a strain rate as near as possible to 1 % of the gauge length per minute. The resulting testing speed for different types of specimens is given in that part of ISO 527 relevant to the material being tested.

9.7 Recording of data

Record the force and the corresponding values of the increase of the gauge length and of the distance between grips during the test. It is preferable to use an automatic recording system which yields complete stress/strain curves for this operation [see clause 10, equations (3), (4) and (5)].

Determine all relevant stresses and strains defined in clause 4 from the stress/strain curve (see figure 1), or using other suitable means.

For failures outside the criteria for an acceptable failure, see 7.2 and 7.3.

10 Calculation and expression of results

10.1 Stress calculations

Calculate all stress values defined in 4.3 on the basis of the initial cross-sectional area of the test specimen:

$$\sigma = \frac{F}{A} \quad \ldots (3)$$

where

- σ is the tensile stress value in question, expressed in megapascals;
- F is the measured force concerned, in newtons;
- A is the initial cross-sectional area of the specimen, expressed in square millimetres.

10.2 Strain calculations

Calculate all strain values defined in 4.4 on the basis of the gauge length:

$$\varepsilon = \frac{\Delta L_0}{L_0} \quad \ldots (4)$$

$$\varepsilon\,(\%) = 100 \times \frac{\Delta L_0}{L_0} \quad \ldots (5)$$

where

- ε is the strain value in question, expressed as a dimensionless ratio, or in percentage;
- L_0 is the gauge length of the test specimen, expressed in millimetres;
- ΔL_0 is the increase in the specimen length between the gauge marks, expressed in millimetres.

The values of the nominal tensile strain, defined in 4.5, shall be calculated on the basis of the initial distance between the grips:

$$\varepsilon_t = \frac{\Delta L}{L} \quad \ldots (6)$$

$$\varepsilon_t\,(\%) = 100 \times \frac{\Delta L}{L} \quad \ldots (7)$$

where

- ε_t nominal tensile strain, expressed as a dimensionless ratio or percentage, %;
- L initial distance between grips, expressed in millimetres;
- ΔL increase of the distance between grips, expressed in millimetres.

10.3 Modulus calculation

Calculate the modulus of elasticity (Young's modulus), defined in 4.6 on the basis of two specified strain values:

$$E_t = \frac{\sigma_2 - \sigma_1}{\varepsilon_2 - \varepsilon_1} \quad \ldots (8)$$

where

- E_t is Young's modulus of elasticity, expressed in megapascals;
- σ_1 is the stress, in megapascals, measured at the strain value $\varepsilon_1 = 0{,}000\,5$;
- σ_2 is the stress, in megapascals, measured at the strain value $\varepsilon_2 = 0{,}002\,5$;

For computer-aided equipment, see 4.6, note 1.

10.4 Poisson's ratio

If required, calculate Poisson's ratio defined in 4.7 on the basis of two corresponding strain values perpendicular to each other:

$$\mu_n = -\frac{\varepsilon_n}{\varepsilon} \quad \ldots (9)$$

where

- μ_n is Poisson's ratio, expressed as a dimensionless ratio with $n = b$ (width) or h (thickness) indicating the normal direction chosen;
- ε is the strain in the longitudinal direction;
- ε_n is the strain in the normal direction, with $n = b$ (width) or h (thickness).

10.5 Statistical parameters

Calculate the arithmetic means of the test results and, if required, the standard deviations and the 95 % confidence intervals of the mean values according to the procedure given in ISO 2602.

10.6 Significant figures

Calculate the stresses and the modulus to three significant figures. Calculate the strains and Poisson's ratio to two significant figures.

11 Precision

See that part of ISO 527 relevant to the material being tested.

12 Test report

The test report shall include the following information:

a) a reference to the relevant part of ISO 527;

b) all the data necessary for identification of the material tested, including type, source, manufacturer's code number and history, where these are known;

c) description of the nature and form of the material in terms of whether it is a product, semifinished product, test panel or specimen. It should include the principal dimensions, shape, method of manufacture, succession of layers and any pretreatment;

d) type of test specimen, the width and thickness of the parallel section, including mean, minimum and maximum values;

e) method of preparing the test specimens, and any details of the manufacturing method used;

f) if the material is in product or semifinished product form, the orientation of the specimen in relation to the product or semifinished product from which it is cut;

g) number of test specimens tested;

h) standard atmosphere for conditioning and testing, plus any special conditioning treatment, if required by the relevant standard for the material or product concerned;

i) accuracy grading of the test machine (see ISO 5893);

j) type of elongation or strain indicator;

k) type of clamping device and clamping pressure, if known;

l) testing speeds;

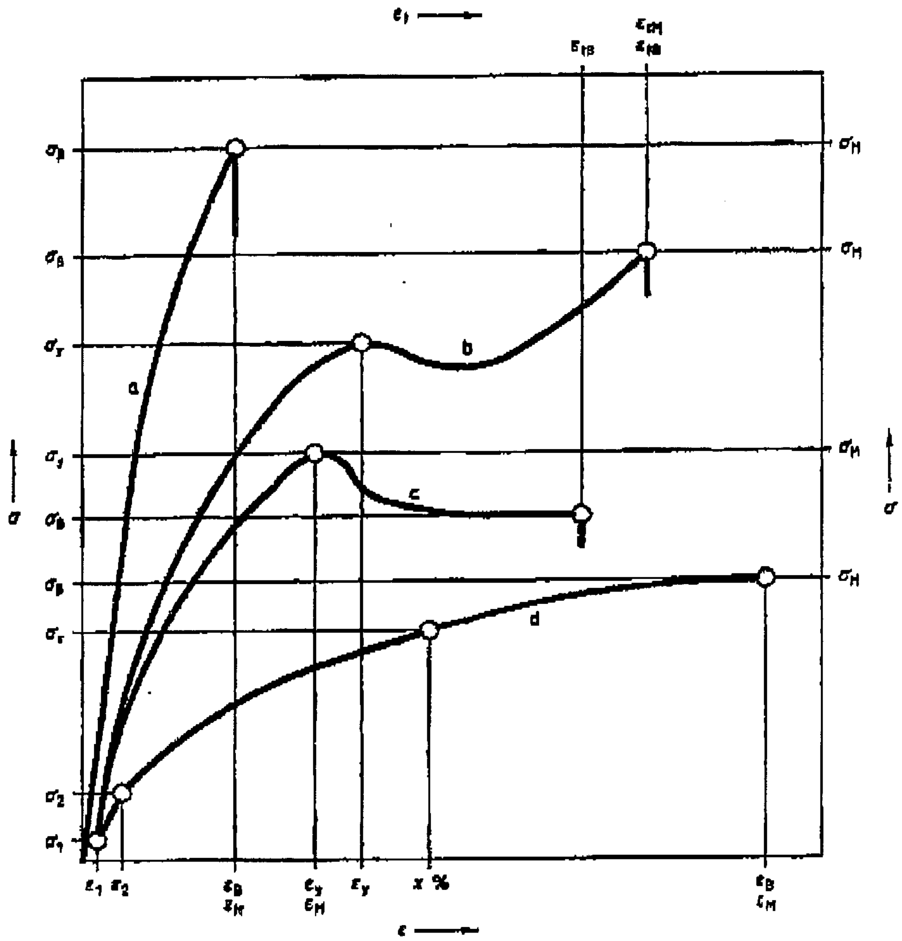
m) individual test results;

n) mean value(s) of the measured property(ies), quoted as the indicative value(s) for the material tested;

o) standard deviation, and/or coefficient of variation, and/or confidence limits of the mean, if required;

p) statement as to whether any test specimens have been rejected and replaced, and, if so, the reasons;

q) date of measurement.



Curve a	Brittle materials
Curves b and c	Tough materials with yield point
Curve d	Tough materials without yield point

The points for the calculation of Young's modulus E_t according to 10.3 are indicated by $(\sigma_1, \varepsilon_1)$ and $(\sigma_2, \varepsilon_2)$, shown only for curve d ($\varepsilon_1 = 0{,}000\ 5$; $\varepsilon_2 = 0{,}002\ 5$).

Figure 1 — Typical stress/strain curves

Annex A
(informative)

Young's modulus and related values

Due to their viscoelastic behaviour many properties of polymer materials depend not only on temperature but also on time. With regard to the tensile test, this causes nonlinear stress/strain curves (bending towards the strain axis) even within the range of linear viscoelasticity. This effect is pronounced in the case of tough polymers. Consequently, the values of the tangent modulus of tough materials taken from the initial part of the stress/strain curves often depend strongly on the scales used. Thus the conventional method (tangent at the initial point of the stress/strain curve) does not give reliable moduli for these materials.

The method for the measurement of Young's modulus prescribed in this part of ISO 527 is based, therefore, on two specified strain values, i.e. 0,25 % and 0,05 %. (The lower strain value has been set at not zero in order to avoid errors in the measured modulus caused by possible onset effects at the beginning of the stress/strain curve.)

In the case of brittle polymers, both the new and the conventional methods give the same values for the modulus. The new method, however, allows accurate and reproducible measurement of the moduli of tough plastics. The definition of the initial tangent modulus, therefore, has been deleted in the present part of ISO 527.

The aspects mentioned above for the modulus similarly relate to the "offset yield point", which in ISO/R 527 was defined by the deviation of the stress/strain curve from its initial linearity. The offset yield point, therefore, is replaced by a point of specified strain (stress at x % strain, σ_x, see 4.3.4). Since the definition of such a "substitute" yield point is significant for tough materials only, the specified strain shall be chosen near the yield strain commonly found.

INTERNATIONAL STANDARD

ISO 527-2

First edition
1993-06-15

Plastics — Determination of tensile properties —

Part 2:
Test conditions for moulding and extrusion plastics

Plastiques — Détermination des propriétés en traction —
Partie 2: Conditions d'essai des plastiques pour moulage et extrusion

Reference number
ISO 527-2:1993(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 527-2 was prepared by Technical Committee ISO/TC 61, *Plastics*, Sub-Committee SC 2, *Mechanical properties*.

Together with the other parts of ISO 527, it cancels and replaces ISO Recommendation R 527:1966, which has been technically revised.

Annex A of this part of ISO 527 cancels and replaces ISO 6239:1986, *Plastics — Determination of tensile properties by use of small specimens*.

ISO 527 consists of the following parts, under the general title *Plastics — Determination of tensile properties*:

— *Part 1: General principles*

— *Part 2: Test conditions for moulding and extrusion plastics*

— *Part 3: Test conditions for sheet and film*

— *Part 4: Test conditions for isotropic and orthotropic fibre-reinforced plastic composites*

— *Part 5: Test conditions for unidirectional fibre-reinforced plastic composites*

Annex A forms an integral part of this part of ISO 527.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Plastics — Determination of tensile properties —

Part 2:
Test conditions for moulding and extrusion plastics

1 Scope

1.1 This part of ISO 527 specifies the test conditions for determining the tensile properties of moulding and extrusion plastics, based upon the general principles given in ISO 527-1.

1.2 The methods are selectively suitable for use with the following range of materials:

- rigid and semirigid thermoplastics moulding, extrusion and cast materials, including compounds filled and reinforced by e.g. short fibres, small rods, plates or granules but excluding textile fibres (see ISO 527-4 and ISO 527-5) in addition to unfilled types;
- rigid and semirigid thermosetting moulding and cast materials, including filled and reinforced compounds but excluding textile fibres as reinforcement (see ISO 527-4 and ISO 527-5);
- thermotropic liquid crystal polymers.

The methods are not suitable for use with materials reinforced by textile fibres (see ISO 527-4 and ISO 527-5), with rigid cellular materials or sandwich structures containing cellular material.

1.3 The methods are applied using specimens which may be either moulded to the chosen dimensions or machined, cut or punched from injection- or compression-moulded plates. The multipurpose test specimen is preferred (see ISO 3167:1993, *Plastics — Multipurpose test specimens*).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 527. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 527 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 37:1977, *Rubber, vulcanized — Determination of tensile stress-strain properties.*

ISO 293:1986, *Plastics — Compression moulding test specimens of thermoplastic materials.*

ISO 294:—[1], *Plastics — Injection moulding of test specimens of thermoplastic materials.*

ISO 295:1991, *Plastics — Compression moulding of test specimens of thermosetting materials.*

ISO 527-1:1993, *Plastics — Determination of tensile properties — Part 1: General principles.*

ISO 1926:1979, *Cellular plastics — Determination of tensile properties of rigid materials.*

ISO 2818:—[2], *Plastics — Preparation of test specimens by machining.*

1) To be published. (Revision of ISO 294:1975)

2) To be published. (Revision of ISO 2818:1980)

3 Principle

See ISO 527-1:1993, clause 3.

4 Definitions

For the purposes of this part of ISO 527, the definitions given in ISO 527-1 apply.

5 Apparatus

See ISO 527-1:1993, clause 5.

6 Test specimens

6.1 Shape and dimensions

Wherever possible, the test specimens shall be dumb-bell-shaped types 1A and 1B as shown in figure 1. Type 1A is preferred for directly-moulded multipurpose test specimens, type 1B for machined specimens.

NOTE 1 Types 1A and 1B test specimens having 4 mm thickness are identical to the multipurpose test specimens according to ISO 3167, types A and B, respectively.

For the use of small specimens, see annex A.

6.2 Preparation of test specimens

Test specimens shall be prepared in accordance with the relevant material specification. When none exists, or unless otherwise specified, specimens shall be either directly compression- or injection moulded from the material in accordance with ISO 293, ISO 294 or ISO 295, as appropriate, or machined in accordance with ISO 2818 from plates that have been compression- or injection-moulded from the compound.

All surfaces of the test specimens shall be free from visible flaws, scratches or other imperfections. From moulded specimens all flash, if present, shall be removed, taking care not to damage the moulded surface.

Test specimens from finished goods shall be taken from flat areas or zones having minimum curvature. For reinforced plastics, test specimens should not be machined to reduce their thickness unless absolutely necessary. Test specimens with machined surfaces will not give results comparable to specimens having non-machined surfaces.

6.3 Gauge marks

See ISO 527-1:1993, subclause 6.3.

6.4 Checking the test specimens

See ISO 527-1:1993, subclause 6.4.

7 Number of test specimens

See ISO 527-1:1993, clause 7.

8 Conditioning

See ISO 527-1:1993, clause 8.

9 Procedure

See ISO 527-1:1993, clause 9.

For the measurement of the modulus of elasticity, the speed of testing shall be 1 mm/min for specimen types 1A and 1B (see figure 1). For small specimens see annex A.

10 Calculation and expression of results

See ISO 527-1:1993, clause 10.

11 Precision

The precision of this test method is not known, because interlaboratory data are not available. When interlaboratory data are obtained, a precision statement will be added with the next revision.

12 Test report

The test report shall include the following information:

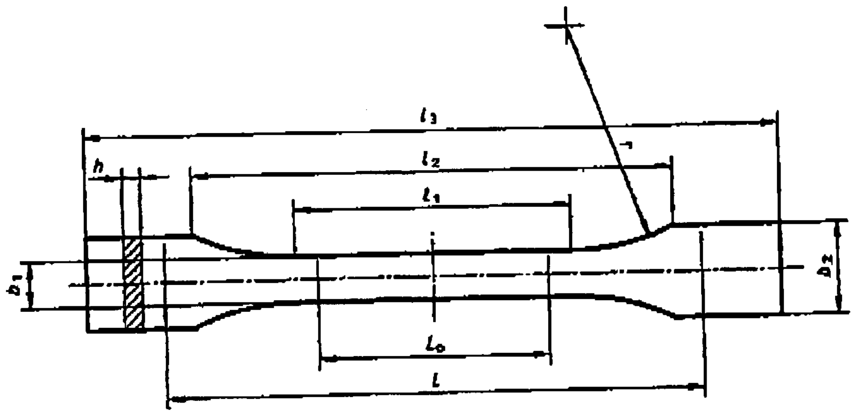
a) a reference to this part of ISO 527, including the type of specimen and the testing speed according to:

Tensile test ISO 527-2/1A/50

Type of specimen (see figure 1)

Testing speed, in millimetres per minute (see ISO 527-1:1992, table 1)

For items b) to q) in the test report, see ISO 527-1:1993, 12 b) to q).



Dimensions in millimetres

	Specimen type	1A	1B
l_3	Overall length	≥ 150 1)	
l_1	Length of narrow parallel-sided portion	80 ± 2	60,0 ± 0,5
r	Radius	20 to 25	≥ 60 2)
l_2	Distance between broad parallel-sided portions	104 to 113 3)	106 to 120 3)
b_2	Width at ends	20,0 ± 0,2	
b_1	Width of narrow portion	10,0 ± 0,2	
h	Preferred thickness	4,0 ± 0,2	
L_0	Gauge length	50,0 ± 0,5	
L	Initial distance between grips	115 ± 1	$l_2{}^{+5}_{0}$

NOTE — Specimen type 1A is preferred for directly-moulded multipurpose test specimens, type 1B for machined specimens.

1) For some materials, the length of the tabs may need to be extended (e. g. l_3 = 200 mm) to prevent breakage or slippage in the testing jaws.

2) $r = [(l_2 - l_1)^2 + (b_2 - b_1)^2]/4\,(b_2 - b_1)$

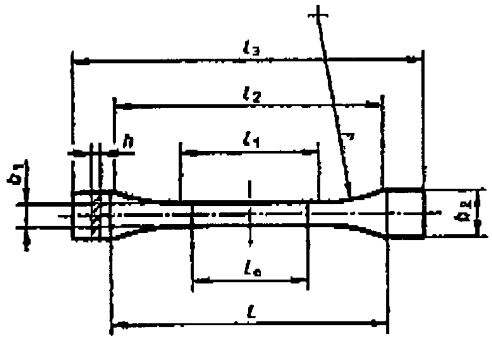
3) Resulting from l_1, r, b_1 and b_2, but within the indicated tolerance.

Figure 1 — Test specimen types 1A and 1B

Annex A
(normative)

Small specimens

If for any reason it is not possible to use a standard type 1 test specimen, specimens of the types 1BA, 1BB (see figure A.1), 5A or 5B (see figure A.2) may be used, provided that the speed of testing is adjusted to the value given in 5.1.2, table 1 of ISO 527-1:1993, which gives the nominal strain rate for the small test specimen closest to that used for the standard-sized specimen. The rate of nominal strain is the quotient of the speed of testing (see 4.2 in ISO 527-1:1993) and the initial distance between grips. Where modulus measurements are required, the test speed shall be 1 mm/min. It may be technically difficult to measure modulus on small specimens because of small gauge lengths and short testing times. Results obtained from small specimens are not comparable with those obtained from type 1 specimens.

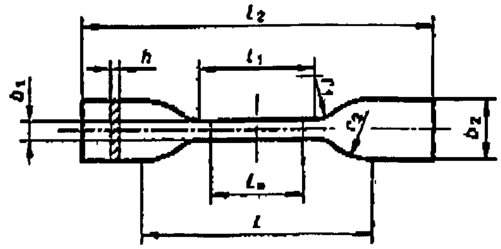


Dimensions in millimetres

	Type of specimen	1BA	1BB
l_3	Overall length	≥ 75	≥ 30
l_1	Length of narrow parallel-sided portion	30 ± 0,5	12 ± 0,5
r	Radius	≥ 30	≥ 12
l_2	Distance between broad parallel-sided portions	58 ± 2	23 ± 2
b_2	Width at ends	10 ± 0,5	4 ± 0,2
b_1	Width of narrow portion	5 ± 0,5	2 ± 0,2
h	Thickness	≥ 2	≥ 2
L_0	Gauge length	25 ± 0,5	10 ± 0,2
L	Initial distance between grips	$l_2{}^{+2}_{0}$	$l_2{}^{+1}_{0}$

NOTE — The specimen types 1BA and 1BB are proportionally scaled to type 1B with a reduction factor of 1:2 and 1:5 respectively with the exception of thickness.

Figure A.1 — Test specimen types 1BA and 1BB



Dimensions in millimetres

	Type of specimen	5A	5B
l_2	Overall length, minimum	≥ 75	≥ 35
b_2	Width at ends	12,5 ± 1	6 ± 0,5
l_1	Length of narrow parallel-sided portion	25 ± 1	12 ± 0,5
b_1	Width of narrow parallel-sided portion	4 ± 0,1	2 ± 0,1
r_1	Small radius	8 ± 0,5	3 ± 0,1
r_2	Large radius	12,5 ± 1	3 ± 0,1
L	Initial distance between grips	50 ± 2	20 ± 2
L_0	Gauge length	20 ± 0,5	10 ± 0,2
h	Thickness	≥ 2	≥ 1

NOTE — Test specimen types 5A and 5B are approximately proportional to type 5 of ISO 527-3 and represent respectively types 2 and 3 of ISO 37.

Figure A.2 — Test specimen types 5A and 5B

INTERNATIONAL STANDARD

ISO 527-3

First edition
1995-08-01

Plastics — Determination of tensile properties —

Part 3:
Test conditions for films and sheets

Plastiques — Détermination des propriétés en traction —
Partie 3: Conditions d'essai pour films et feuilles

Reference number
ISO 527-3:1995(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 527-3 was prepared by Technical Committee ISO/TC 61, *Plastics*, Subcommittee SC 11, *Products*.

Together with the other parts of ISO 527, it cancels and replaces ISO Recommendation R/527:1966, as well as ISO 1184:1983, of which it constitutes a technical revision.

ISO 527 consists of the following parts, under the general title *Plastics — Determination of tensile properties*:

— *Part 1: General principles*

— *Part 2: Test conditions for moulding and extrusion plastics*

— *Part 3: Test conditions for films and sheets*

— *Part 4: Test conditions for isotropic and orthotropic fibre-reinforced plastic composites*

— *Part 5: Test conditions for unidirectional fibre-reinforced plastic composites*

International Organization for Standardization
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Printed in Switzerland

Plastics — Determination of tensile properties —

Part 3:
Test conditions for films and sheets

1 Scope

1.1 This part of ISO 527 specifies the conditions for determining the tensile properties of plastic films or sheets less than 1 mm thick, based upon the general principles given in part 1.

NOTE 1 For sheets greater than 1 mm thick, the user is referred to part 2 of this International Standard.

1.2 See ISO 527-1, subclause 1.2.

1.3 This part of ISO 527 is not normally suitable for determining the tensile properties of:

a) cellular materials;

b) plastics reinforced by textile fibres.

1.4 See ISO 527-1, subclause 1.5.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 527. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 527 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 527-1:1993, *Plastics — Determination of tensile properties — Part 1: General principles.*

ISO 4591:1992, *Plastics — Film and sheeting — Determination of average thickness of a sample, and average thickness and yield of a roll, by gravimetric techniques (gravimetric thickness).*

ISO 4593:1993, *Plastics — Film and sheeting — Determination of thickness by mechanical scanning.*

3 Principle

See ISO 527-1, clause 3.

4 Definitions

See ISO 527-1, clause 4.

5 Apparatus

See ISO 527-1, clause 5, subject to the following additional requirements:

In 5.1.2, the tensile-testing machine shall be capable of maintaining the speeds of testing as specified in table 1 of ISO 527-1. It is normal for films and sheets to be tested at a speed of 5 mm/min, 50 mm/min, 100 mm/min, 200 mm/min, 300 mm/min or 500 mm/min. The information contained in ISO 527-1, subclause 9.6, also applies.

In 5.1.5, when testing thin sheets or film material, the specimen shall not carry the weight of the extensometer.

In 5.2, devices complying with the requirements in ISO 4593 shall be used for measuring the thickness, except in the case of very thin film (less than 0,01 mm thick) or embossed film. In those cases, the thickness shall be determined by the method specified in ISO 4591. When ISO 4591 is used, the average thickness of the film sample shall be taken as the thickness of the test specimen.

6 Test specimens

6.1 Shape and dimensions

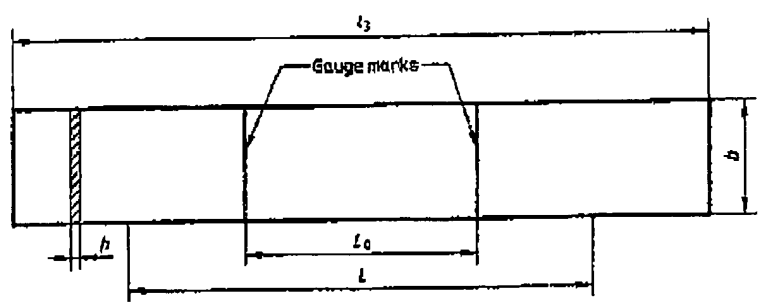
6.1.1 The preferred form of test specimen for the determination of tensile properties by this method is a strip 10 mm to 25 mm wide and not less than 150 mm long (specimen type 2 — see figure 1), having two parallel gauge marks, 50 mm apart, on the central portion of the specimen.

Some film materials have a very high elongation at break which may result in them being outside the stretching capacity of the testing machine. In such cases, it is permissible to reduce the initial distance between the grips to 50 mm.

6.1.2 When required by the specification for the material under test or for routine quality-control tests, dumb-bell specimen types 5, 1B and 4 of the shape and dimensions shown in figures 2, 3 and 4 may be used. These specimens are convenient to produce and permit rapid quality-control testing.

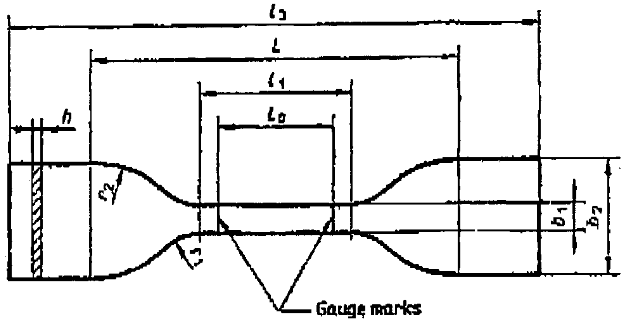
Specimen type 5 (figure 2) is recommended for film and sheet with a very high strain at break. Specimen type 4 is recommended for other types of flexible thermoplastic sheet.

Specimen type 1B (figure 3) is recommended for rigid sheets.



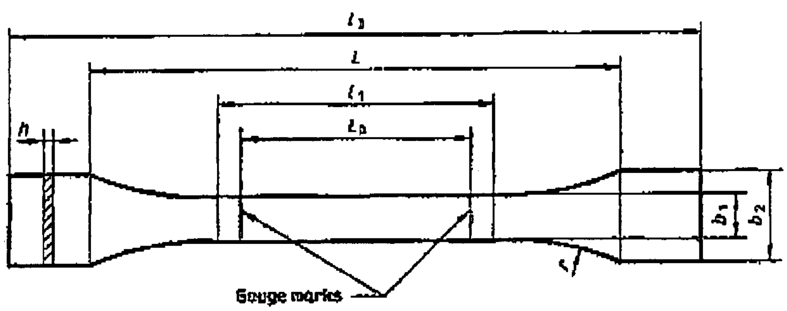
b	Width: 10 mm to 25 mm
h	Thickness: ≤ 1 mm
L_0	Gauge length: 50 mm ± 0,5 mm
L	Initial distance between grips: 100 mm ± 5 mm
l_3	Overall length: ≥ 150 mm

Figure 1 — Specimen type 2



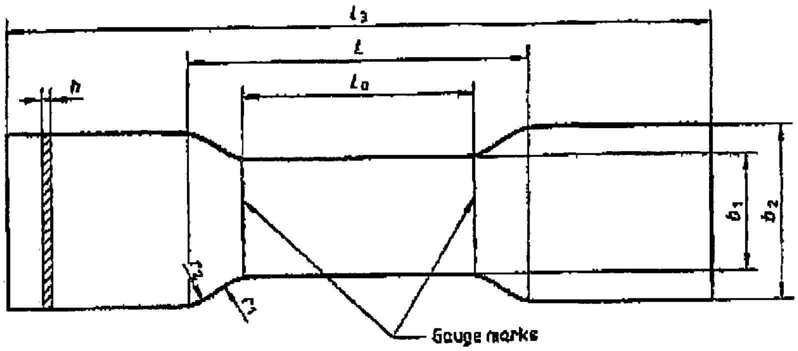
- b_1 Width of narrow parallel-sided portion: 6 mm ± 0,4 mm
- b_2 Width at ends: 25 mm ± 1 mm
- h Thickness: ⩽ 1 mm
- L_0 Gauge length: 25 mm ± 0,25 mm
- l_1 Length of narrow parallel-sided portion: 33 mm ± 2 mm
- L Initial distance between grips: 80 mm ± 5 mm
- l_3 Overall length: ⩾ 115 mm
- r_1 Small radius: 14 mm ± 1 mm
- r_2 Large radius: 25 mm ± 2 mm

Figure 2 — Specimen type 5



- b_1 Width of narrow parallel-sided portion: 10 mm ± 0,2 mm
- b_2 Width at ends: 20 mm ± 0,5 mm
- h Thickness: ⩽ 1 mm
- L_0 Gauge length: 50 mm ± 0,5 mm
- l_1 Length of narrow parallel-sided portion: 60 mm ± 0,5 mm
- L Initial distance between grips: 115 mm ± 5 mm
- l_3 Overall length: ⩾ 150 mm
- r Radius: ⩾ 60 mm

Figure 3 — Specimen type 1B



b_1 Width of narrow parallel-sided portion: 25,4 mm ± 0,1 mm
b_2 Width at ends: 38 mm
h Thickness: ≤ 1 mm
L_0 Gauge length: 50 mm ± 0,5 mm
L Initial distance between grips: 73,4 mm
l_3 Overall length: 152 mm
r_1 Small radius: 22 mm
r_2 Large radius: 25,4 mm

Figure 4 — Specimen type 4

6.2 Preparation of specimens

6.2.1 The test specimens described in 6.1.1 shall be cut or punched so that the edges are smooth and free from notches; examination with a low-power magnifier is recommended to check the absence of notches. Razor blades, suitable paper cutters, scalpels or other devices capable of cutting the specimens to the proper width and producing straight, clean, parallel edges with no visible imperfections shall be used. Punch dies shall be kept sharp by regular honing, and a suitable backing material shall be used with punch dies to ensure a clean-cut edge.

6.2.2 The test specimens described in 6.1.2 shall be obtained by the use of punch dies, using suitable backing material to ensure a clean-cut edge. Dies shall be kept sharp by regular honing, and the edges of the specimen shall be examined with a low-power magnifier to ensure the absence of notches. Discard any specimen with obvious imperfections on the cut edges.

6.3 Gauge marks

See ISO 527-1, subclause 6.3.

The marking device used to produce the gauge marks shall have two parallel edges which are ground smooth and true, 0,05 mm to 0,10 mm wide at the edge and bevelled at an angle of not more than 15°. An ink stamp may also be used to apply ink to the area of the gauge marks, before or after producing them with the marking device, using an ink of a suitable contrasting colour that has no deleterious effect on the film being tested.

6.4 Checking the specimens

Discard any test specimen with obvious imperfections on the cut edges.

6.5 Anisotropy

The properties of certain types of film material may vary with direction in the plane of the film (anisotropy). In such cases, it is essential to prepare two groups

of test specimens with their major axes respectively parallel and perpendicular to the direction of orientation of the film.

7 Number of specimens

See ISO 527-1, clause 7.

8 Conditioning

See ISO 527-1, clause 8.

9 Procedure

See ISO 527-1, clause 9.

10 Calculation and expression of results

See ISO 527-1, clause 10, except for "10.3 Modulus calculation", and "10.4 Poisson's ratio, μ".

11 Precision

The precision of the test method is not known because inter-laboratory data are not available. When inter-laboratory data are obtained, a precision statement will be added at the following revision.

12 Test report

The test report shall include the following information:

a) a reference to this part of ISO 527, including the type of specimen and the test speed, written in the following format:

```
Tensile test                               ISO 527-3/1B/50
                                                      |  |
Type of specimen  ------------------------------------+  |
                                                         |
Test speed in millimetres per minute --------------------+
```

b) to q) see ISO 527-1, clause 12, b) to q).

ICS 83.140

Descriptors: plastics, films, plastic sheets, tests, determination, tensile properties, testing conditions, test specimens.

Price based on 5 pages

September 1998

Berichtigungen zu DIN EN ISO 527-3 : 1995-10 (EN ISO 527-3 : 1995/AC : 1998)	Berichtigung 1 zu DIN EN ISO 527-3

ICS 83.140.10

Deskriptoren: Kunststoffolie, Tafel, Prüfung, Eigenschaft, Zugversuch

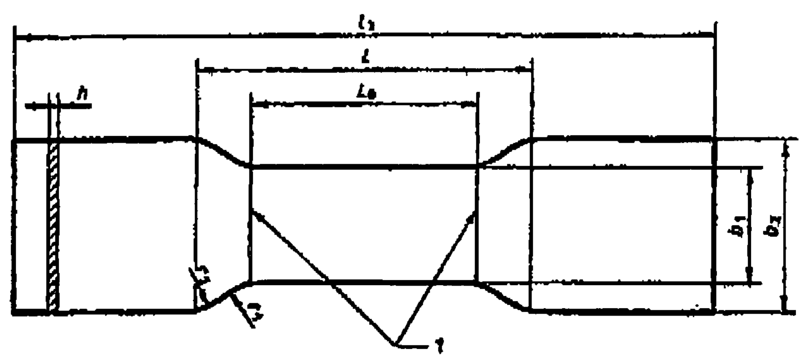
Corrigenda to DIN EN ISO 527-3 : 1995-10
(EN ISO 527-3 : 1995/AC : 1998)

Corrigenda à DIN EN ISO 527-3 : 1995-10
(EN ISO 527-3 : 1995/AC : 1998)

Es wird empfohlen, auf der betroffenen Norm einen Hinweis auf diese Berichtigung zu machen.

In
DIN EN ISO 527-3
Kunststoffe – Bestimmung der Zugeigenschaften – Teil 3: Prüfbedingungen für Folien und Tafeln (ISO 527-3 : 1995); Deutsche Fassung EN ISO 527-3 : 1995

ist aufgrund des ISO 527-3 : 1995/Cor. 1 : 1998 im Bild 4 (wie folgt dargestellt) das Maß L von 73,4 mm in 98 mm zu berichtigen:



1	Meßmarken	
b_1	Breite des engen parallelen Teils:	25,4 mm ± 0,1 mm
b_2	Breite an den Enden:	38 mm
h	Dicke:	≤ 1 mm
L_0	Meßlänge:	50 mm ± 0,5 mm
L	Anfangsabstand der Einspannklemmen:	98 mm
l_3	Gesamtlänge:	≥ 152 mm
r_1	kleiner Radius:	22 mm
r_2	großer Radius:	25,4 mm

Bild 3: Probekörper der Typen A und B

Normenausschuß Kunststoffe (FNK) im DIN Deutsches Institut für Normung e.V.

Ref. Nr. DIN EN ISO 527-3 : 1995-10/Ber 1 : 1998-09

DIN 58950-1

GERMAN STANDARD **April 2003**

Sterilization

Steam sterilizers for pharmaceutical products

Part 1: Terminology

Content Page

Continuation page 2 to 16

Standards Committee Medicine (NAMed) in DIN German Institute for Standardisation e.V.

Preface

This standard was developed by the Standards Committee Medicine (NaMED) in DIN German Institute for Standardisation e.V., working committee D5 "sterilizers for pharmaceutical products".

DIN 58950 *"Sterilization – Steam Sterilizers for Pharmaceutical Products"* consists of:

- *Part 1: Terminology*
- *Part 2: Equipment requirements*
- *Part 3: Tests*
- *Part 6: Operation*
- *Part 7: Operating equipment and structural requirements*

Appendices A and B are informative.

Changes

The following changes are made compared with DIN 58950-1995-08:

a) The following terms and definitions were cancelled:

   Basic operations, performance certificate, program paragraph, program step, process step, pre-acceptance for steam sterilizers for pharmaceutical products;

b) The term "sterilization safety" was included;

c) Appendix B with process diagrams for exemplary sterilization processes was amended;

d) The content was completely revised.

Earlier issues

DIN 58950-1: 1986, 1995-08

1 Application

This standard applies to sterilizers for pharmaceutical products.

2 Normative references

By way of dated or undated references this standard contains determinations from other publications. These normative references are cited at the respective points in the text and the publications are mentioned below. In the case of dated references subsequent amendments or revisions of such publications apply only to that standard if incorporated through amendment or revision. In the case of undated references the last edition of the publication referred to applies (including amendments).

DIN 1319-1:1995, *Fundamentals of measurement technology – Part 1: Basic terms.*

DIN 1319-3, *Fundamentals of measurement technology – Part 3: Evaluations of measurements of an individual measurand, measurement uncertainty.*

DIN 31051, *Fundamentals of maintenance.*

DIN 58900-1, *Sterilization – general fundamentals – terms*

DIN 58946-1, *Sterilization – steam sterilizers for medical products – terms.*

DIN 58950-7:2003-04 Sterilization – steam sterilizers for pharmaceutical products – Part 7: Operating equipment requirements and structural requirements.

Ordinance for the simplification in the area of safety and health protection in the provision of working equipment and its use at work, safety in the operation of plants requiring monitoring and organisation of industrial safety of 27th September 2002 (industrial safety ordinance) [1].

3 Terminology

The application of this standard is subject to the general terms of sterilization provided in DIN 58900-1, the terms of steam sterilization specified in DIN 58946-1, the terms specified in DIN 31051 and the following terms.

Terms for which definitions are included at another point in this standard are marked with an *.

3.1
Reference temperature
T_b
Temperature forming the base for the calculation of the degree of lethality*

NOTE At the reference temperature the degree of lethality has the value 1.

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1) Federal Gazette 2002 Part 1 No. 70, 2nd October 2002.

3.2

Direct hot water spray process

DBHV

Process stage* for sterilizing where the sterilization water* is circulated as heat transfer medium for the heating of the product to be sterilized

3.2

Direct hot water cooling

DHK

Process stage* for cooling where the sterilization water* is circulated as heat transfer medium for the cooling of the product to be sterilized

3.4

Steam injection process

DIJV

Process stage* for sterilization where the air is displaced from the sterilization chamber through one-off evacuation and simultaneous inflow of minor quantities of steam and steam inflow subsequently continues until the working pressure has been attained

3.5

Steam-air mixture process

DLGV

Process stage* for sterilization where a steam-air mixture is used as heat transfer medium for the heating of the product to be sterilized

3.6

Steam-air mixture cooling

DLK

Process stage* for cooling where a steam-air mixture is used as heat transfer medium for the cooling of the product to be sterilized

3.7

***D*-value**

Decimal reduction time

Time span in which the number of microorganisms capable of reproduction decreases by a power of 10 at a certain temperature under defined conditions

NOTE 1 The time span is specified in minutes.

NOTE 2 Specification of D-values is only practical for pure cultures.

3.8

Specialist for steam-sterilizers for pharmaceutical products

Person who, based on his/her technical training, possesses knowledge and experience on steam sterilizers for pharmaceutical products and is able to evaluate the tasks assigned to him/her and recognise possible hazards

NOTE The specialist qualification is generally certified by the necessary completion of training such as engineer, master, tradesman. Several years of activity in the scope of work concerned can also be utilised to evaluate the technical training.

3.9
Fractional vacuum with drying
FVT
Process stage* for drying where the chamber is repeatedly evacuated and ventilated with sterile filtered air and heat is simultaneously supplied by way of the chamber jacket.

3.10
Fractional vacuum process
FRVV
Process stage* for sterilization where evacuation takes place repeatedly alternating with steam inflow and steam inflow subsequently continues until the working pressure has been attained

3.11
***F*-value**
Time required in minutes necessary at the reference temperature* to kill a quantity of microorganisms capable of reproduction

NOTE 1 The *F*-value achieved for the sterilization effect is calculated according to equation (1).

$$F = \qquad (1)$$

where

L is the degree of lethality* according to the measuring point;
Δt is the time interval in minutes

NOTE 2 The *F*-value required for germ reduction is calculated according to equation (2)

$$F = \qquad (2)$$

where

D is the *D*-value* in minutes;
N_A the original germ number;
N_E the desired number of germs.

NOTE 3 A *D*-value of at least 1.5 is demanded in the European pharmacopoeia.

3.12
***Fo*-value** (2)
F-value*, the calculation of which is based on a reference temperature* of 121° C and a z-value* of 10 K

NOTE The F_o-value is calculated according to the equation (3):

$$F_o = \qquad (3)$$

where

T_i is the measurement point temperature* in degree Celsius;

Δt is the time interval in minutes;
z is the z-value in Kelvin

3.13
Limit temperature
T_g
the lowest temperature from which the calculation of the F-value* is started

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2) See Appendix A

3.14
Heating steam
Steam which is generally used for heat supply and generated in boilers

NOTE Hot steam can be saturated steam or superheated steam.

3.15
Adjusting
Adjusting or tuning a measuring instrument to eliminate systematic measurement deviations to the extent required for the intended application [DIN 1319-1:1995-01, term 4.11]

3.16
Calibrating
Determining the relationship between the measured value or expected value of the output quantity and the applicable true or correct value of the measurand available as input quantity for a measuring facility under consideration with given conditions [DIN 1319-1995-01, term 4.10]

NOTE No intervention changing the measuring instrument takes place during calibration.

3.17
Degree of lethality
L
Dimension for the germ-killing effectiveness at a certain temperature based on the reference temperature*

NOTE The degree of lethality is calculated according to the equation (4).

$$L_i = \qquad (4)$$

where

L_i is the degree of lethality at the measuring point temperature* T_i,
T_i is the measuring point temperature* in degree Celsius;
T_b is the reference temperature* in degree Celsius;
z is the z-value* in Kelvin.

3.18
Measuring point temperature

T_1
Temperature measured at a certain time at a certain point in the product to be sterilized

3.19
Pharmaceutical pure steam
Steam which, because of its particular pureness, is suitable for directly acting on the products to be sterilized of Group II according to DIN 58950-7:2003-04, Table 2

3.20
Pharmaceutical products to be sterilized
All products and items to be sterilized in the pharmaceutical area

NOTE DIN 58950-2-2003-04, Table 1, and DIN 58950-6-2003-04, Paragraph 4, and DIN 58950-7:2003-04, Table 2, contain listings of these products to be sterilized according to various allocation criteria.

3.21
Qualifying
The formal and systematic certification of the efficiency and the suitability of the steam sterilizer for the intended purpose

NOTE Qualifying is subdivided into qualifying the installation and qualifying the function and performance

3.22
Expert for steam sterilizers for pharmaceutical products
Person who, based on his/her technical training and experience, has adequate knowledge of steam sterilizers and is familiar with the applicable industrial safety provisions, accident prevention regulations, guidelines and the generally accepted rules of engineering (e.g. DIN VDE standards, DIN standards) to the extent that he/she is able to evaluate the condition of a steam sterilizer in terms of occupational and sterilization safety

3.23
Expert inspection
Inspection prior to start-up and recurring inspection of steam sterilizers for pharmaceutical products through experts or approved supervisory organisation according to the Operational Safety Act

3.24
Sterilization process[3)]
Established combination of process stages* for the purpose of sterilization

3.25
Sterilization program
Parametrized combination of process stages* for the purpose of sterilization

3.26
Sterilization steam

Steam with minor contaminations suitable for directly acting on goods to be sterilized of Group I according DIN 58950-7:2003-04, Table 2

3.27
Sterilization parameter
Parameters for the measurement of sterilization processes* among them temperature, pressure and time quantities

3.28
Sterilization water
Water directly acting on the product to be sterilized, e.g. during direct hot water spraying process and on direct hot water cooling

3.29
Sterilization safety
SAL-value[4])
Safety value where the sterilization process concerned converts a quantity of preparations into sterile preparations

3) See Appendix B.
4) SAL = sterility assurance level

NOTE The SAL value of a certain process is expressed as probability of finding a non-sterile preparation among a quantity of preparations. An SAL-value of 10^{-6} for instance indicates the probability of finding a maximum of one non-sterile vessel in a quantity of 10^{6} sterilized preparations of a final product.

3.30
Instructed person
Person for steam sterilizers for pharmaceutical products who has been instructed with regard to the tasks assigned to him/her

NOTE Refer also Accident Prevention Regulation VGB 5.

3.31
Validation [5]) of the process
Proof in agreement with the principles of sound manufacturing practice that processes, pieces of equipment, materials, operations or systems actually lead to the expected results

NOTE Validation is sub-divided into product-related validation and validation of the program control. Validation includes qualifying.

3.32
Process stage
Process stages or temporally joined combinations of process steps as part of the sterilization process

3.33
Vacuum with drying
VMT
Process step* for drying where the chamber is evacuated with the simultaneous supply of heat

3.34
Vacuum without drying
VOT
Process stage* for the removal of the steam through evacuation of the chamber without dwell time

3.35
Pre-vacuum process
VOVV
Process stage* for sterilization where the sterilization chamber is evacuated and subsequently followed by the inflow of steam until the working pressure has been attained

3.36
Water for indirect cooling
Water not coming into direct contact with the product to be sterilized

3.37
z-value
Temperature differential in Kelvin where the *D*-value changes by the factor 10

5) From "The Regulation of Drugs in the European Community", Volume IV, Guideline to sound manufacturing practice for drugs; ISBN 928263178-8.